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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

JOSE CHUNG LUO, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

SPECTRUM PHARMACEUTICALS, INC., JOSEPH W. TURGEON, KURT A. GUSTAFSON, FRANCOIS J. LEBEL, M.D., and THOMAS J. RIGA,

Defendants.

CASE NO. 2:21-cv-01612-CDS-BNW

DEFENDANTS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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Because Plaintiff cannot meaningfully dispute the absence of particularized allegations to support fraud, it repeatedly invites the Court to lower its PSLRA burden. But as the Ninth Circuit has explained, the Court should "assiduously examine Plaintiff['s] pleadings and all the reasonable inferences they support to determine whether the[] complaint satisfie[s] the rigorous and unusual test mandated by Congress in this specialized area of the law." *In re LifeLock, Inc. Sec. Litig.*, 690 F. App'x 947, 949 (9th Cir. 2017). The SAC does not pass that test.[1]

To accept Plaintiff's strained interpretations of Defendants' statements concerning the MD Anderson trial would require the Court to ignore the context in which those statements were made. None of the challenged statements misrepresented the drug's approval threshold or how it compared to existing treatments. Plaintiff's ZENITH20 claims lack allegations of fact showing that "fully confirmed" "final" study results were available to Defendants, much less that any Individual Defendant knew them. Finally, Plaintiff's Rolontis claims fail because Spectrum accurately disclosed the reason for the first BLA application's withdrawal, and because the remainder of the Rolontis claims rely on vague and limited CW allegations that fall far short of meeting Plaintiff's burden to plead with particularity that Defendants' statements misrepresented the Hanmi facility's readiness for FDA inspection.

I. *The Opposition Shows Plaintiff's Failure to Plead an MD Anderson Claim.*

A. The Opposition Confirms Plaintiff's Failure to Plead Any Misstatement.

Working backwards from the premise that the FDA ultimately failed to approve Pozi, Plaintiff scours Defendants' statements on various investor calls to identify any that could conceivably be contorted into a falsity. But "[d]isclosure is required under [Section 10(b)] only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 264 (2024) (quoting 17 C.F.R. § 240.10b-5(b)). Defendants had no duty to disclose

[1] Abbreviations and capitalized terms that are not defined in this reply have the same meaning as in Defendants' Motion to Dismiss. Citations to "¶" or "¶¶" refer to the paragraphs of the SAC. Citations to "Ex." refer to the exhibits to the Declaration of John B. Lawrence filed contemporaneously with Defendants' Motion to Dismiss. Unless otherwise noted, all emphasis is added, and all internal quotations and citations are omitted.

(1) information that bore little to no relation to the subject of Defendants' remarks, nor (2) information that Defendants did not have.

i. Plaintiff did not Plead Misleading Statements about Existing Treatments.

"Critically, plaintiff must demonstrate that a particular statement, when *read in light of all the information then available* to the market . . . conveyed a false or misleading impression." *In re Intel Corp. Sec. Litig.*, 2019 WL 1427660, at *10 (N.D. Cal. Mar. 29, 2019) (quoting *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 512 (9th Cir. 1991)). Plaintiff cannot dispute that the Court should look to context in evaluating Defendants' statements; instead, Plaintiff asks the Court to arbitrarily limit what context is relevant to suit Plaintiff's own version of events. Opp. at 7-8.

First, statements "made prior to the Class Period are relevant to an understanding of the statements made during the Class Period." *Georgia Firefighters' Pension Fund v. Anadarko Petroleum Corp.*, 514 F. Supp. 3d 942, 952 (S.D. Tex. 2021) (rejecting objection to court's consideration of pre-class period statements because they provided "background and context" that informed the meaning of later challenged statements). Plaintiff cites no authority to the contrary. *Second*, Plaintiff's suggestion that investors would not know "to connect the alleged statements to Dr. Heymach's disparate 'context'" is belied by the very call transcripts Plaintiff incorporated by reference into the SAC. *See* ECF 106 at 7 (acknowledging the Court may consider the full contents of the call transcripts containing the challenged statements). *Every one* of those transcripts—in close proximity to the challenged statements—referenced the data Dr. Heymach presented.[2]

Defendants agree with Plaintiff that the Court should look to "the plain language of the statements." Opp. at 7. But looking to the "plain language" *requires* consideration of the relevant

[2] *See* ¶¶ 166-168, 171-172; *see also, e.g.*, Ex. 3 at 5 ("In the fourth quarter of 2017, preliminary data from a Phase II study at MD Anderson Cancer Center was presented at the World Conference on Lung Cancer in Japan."); Ex. 4 at 10 ("Well, what's been presented has been . . . the first 11 patients."); Ex. 5 at 6 ("And that's probably why in this data out now on this from MD Anderson, why they think we're having the early response rates, that [are] so exciting, that you're seeing . . . This is the first 11 patients that caused the stir first at the World Lung last year"); Ex. 6 at 9 (Analyst: "Will [the forthcoming MD Anderson data update] be more than 11 patients in the abstract?" Turgeon: "[I]t will be . . . I think you'll see much more data than you've seen in the past."); Ex. 7 at 7 ("Let me provide some highlights from the data that Dr. Heymach presented at the conference . . . This compares favorably to an overall response rate of less than 10% with available TKIs and a rate of less than 20% with the current standard of care second-line agents.").

context, not ignoring it.[3] *See, e.g.*, *In re Sorrento Therapeutics, Inc. Sec. Litig.*, 97 F.4th 634, 641 (9th Cir. 2024) ("fair reading" of statements "in context" revealed they were not misleading).[4]

Nor does reference to relevant context transform the argument into a "truth-on-the-market defense." Opp. at 8 n.4. Defendants do not claim "[Plaintiff] knew the truth," but rather that additional relevant statements "add important context to the nature of the [challenged] statements." *Gagnon v. Alkermes PLC*, 2019 WL 2866113, at *3 (S.D.N.Y. July 2, 2019); *accord Chang v. Accelerate Diagnostics, Inc.*, 2016 WL 3640023, at *5 (D. Ariz. Jan. 28, 2016) ("Defendants assert that the statements themselves, read in context, are simply not false or misleading. This is not a truth-on-the-market defense."); *Intel Corp.*, 2019 WL 1427660, at *13 n.18 (same).

ii. Plaintiff did not Plead Misleading Statements about the Approval Target.

Plaintiff fails to adequately allege that reasonable investors would interpret or rely on Turgeon's anecdote as announcing or guaranteeing the FDA's threshold for Pozi approval. Opp. at 9; ¶ 175. In *Gagnon*, for example, the defendant pharmaceutical company made statements that patients "will not" and "cannot" relapse while taking its medication for opioid dependence. *Gagnon v. Alkermes PLC*, 368 F. Supp. 3d 750, 770 (S.D.N.Y. 2019). The court held that although the company's statements implied "assurance against relapse"—"read literally and in a vacuum"—"no reasonable investor could plausibly recognize them as such in the context in which they were

[3] Plaintiff attempts to attack certain of Turgeon's statements, ¶ 168, by declaring that "[c]hemotherapy alone returned an ORR of up to 19%." Opp. at 7 n.3. Plaintiff's exhibit does not support that. Plaintiff also singles out Riga's August 9, 2018 response to an analyst question regarding whether the FDA and Spectrum had agreed to a "PFS [Progression Free Survival] hurdle." Opp. at 7 (citing ¶ 171). But "it is clear in context that [Riga] was . . . refusing to take a position." *Bodri v. GoPro, Inc.*, 252 F. Supp. 3d 912, 927 & n.5 (N.D. Cal. 2017); *see also* Ex. 6 at 9-10.

[4] Plaintiff's reliance on *Iso Ray* is misplaced. Opp. at 8. In a press release publicizing its drug's results in a third-party study comparing various treatments, the defendant company allegedly misled investors that its drug provided an "added benefit" over the other treatments, when in fact there was no statistical difference. *In re Iso Ray, Inc. Sec. Litig.*, 189 F. Supp. 3d 1057, 1067-68 (E.D. Wash. 2016). The defendants did not dispute their statements left the impression of an added benefit, but contended it was in fact true that their drug provided an added benefit, for other reasons not mentioned in the press release but that could be ascertained from the study. *Id.* at 1069-70. The press release included a link to an abstract of the study, but not to the study itself that included the data supposedly showing this added benefit. *Id.* at 1066, 1070. The Court held that, while defendants' theory "may be a reasonable interpretation of the results of the study," defendants had omitted information necessary for investors to judge this supposed benefit. *Id.* Here, Defendants do not argue that a third-party document proves a fact Plaintiff believes to be false is actually true, but rather that viewing Defendants' own public statements in the context of Defendants' other public statements, as a reasonable investor does, dispels the argument that they created a false impression.

made." *Id.*; *Gagnon*, 2019 WL 2866113, at *3-4 ("plaintiff cannot simply use the motion to dismiss standard [drawing favorable inferences] to transform a non-actionable statement into an actionable statement by peddling an implausible reading shorn of context").

Turgeon's statements are also puffery and are in an entirely different qualitative league than the statements at issue in *Quality Systems*.[5] Opp. at 9 (citing *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130 (9th Cir. 2017)). By contrast, *Hoey v. Insmed Inc.*, 2018 WL 902266, at *18 (D.N.J. Feb. 15, 2018) is directly on point. There, the plaintiff challenged a similar anecdote similarly recounted by the defendant pharmaceutical company's CEO. *Id.* ("I think one of the nice things about this company two and a half years ago when I had the privilege to talk to the board and to look at the opportunity was, I saw an approvable drug, bottom line."). The court held that "a reasonable investor *would not rely* on this statement" because "it clearly embodies the opinion of [CEO], and amounts to nothing more than a 'gut feeling' stemming from a vaguely described interaction with [company's] corporate board, *at a time before conducting a Phase 2 Trial*." *Id.*

iii. Plaintiff did not Plead any Baseless Optimism About BTD.

Plaintiff concedes its challenge to Riga's November 8, 2018 statements, ¶ 178, hinges entirely on its claim that "Riga knew Pozi needed to demonstrate more than 43% ORR . . . in order to secure BTD status." Opp. at 9-10. But Plaintiff's factual "support" for this claim is non-existent. For example, Plaintiff speculates that Riga's reference to "statistics" *must* mean the precise ORR threshold for BTD, *see id.*, as opposed to any of the myriad other statistics associated with a study like this. Plaintiff posits further that "it makes no sense that Riga would need private conversations with the FDA to learn the generally understood BTD standard." Opp. at 10. Plaintiff's conjecture ignores that Riga stated *on this same call* that "our conversations with the agency are *pretty broad at this point*," Ex. 6 at 9, and Plaintiff's argument is a non-sequitur: Even if "criteria" meant something more specific, there are no factual allegations supporting that "criteria" meant the FDA's *exact BTD threshold*. Ex. 4 at 11. The PSLRA demands more than Plaintiff's unsupported

[5] *Quality Systems* involved the CEO's repeated assurances of a "full and growing" pipeline of "greenfield sales" and "plentiful" opportunities, with "nothing drying up [or] slowing down," in contrast to detailed allegations of contradictory sales data and the CEO's private admissions that the greenfield market was "saturated." *See Quality Sys.*, 865 F.3d at 1136, 1143-44, 1147-48.

assumption. *See Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1194 (9th Cir. 2021) (referring to "production car" did not admit those cars were produced using the fully automated process the disclosures also discussed); *Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 622 (9th Cir. 2022) (knowledge of "inadvertent data-sharing" did not mean awareness of "software bugs").

B. The Opposition Confirms Plaintiff's Failure to Plead Scienter.

The Ninth Circuit held in *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020) that Plaintiff's theory—that Defendants "were promising [BTD] for a medical device application they knew was 'unapprovable'"—is "irrational" and "make[s] [no] sense." Opp. at 11; MTD at 13. Plaintiff does not even attempt to distinguish *Nguyen*. As in *Nguyen*, here there are no plausible allegations of motive that might give this strained theory "more legs." 962 F.3d at 415; *Prodanova v. H.C. Wainwright & Co., LLC*, 993 F.3d 1097, 1108 (9th Cir. 2021) ("the lack of a plausible motive *certainly makes it much less likely* that a plaintiff can show a strong inference of scienter").

Tacitly acknowledging this weakness, Plaintiff meagerly offers just one purported "motive": that "Spectrum was a small company that could not afford bad news." Opp. at 11 (citing ¶¶ 2-3). But that "motive" is both illogical and legally irrelevant. Even under Plaintiff's version of events, there was no "bad news" to "conceal." *Id.* Throughout the MD Anderson statements, Pozi was exceeding Plaintiff's own alleged threshold for FDA approval by *double digits*. Ex. 5 at 6; ¶ 172. Plaintiff pleads no compelling reason for Defendants to low-ball the target. And Riga's later statements on November 8, 2018 about BTD could not reflect a "reckless" "gamble," Opp. at 11, whereby Riga banked on the "chance that the situation regarding [the BTD application] would right itself." *Makor Issues & Rts., Ltd. v. Tellabs Inc.*, 513 F.3d 702, 710 (7th Cir. 2008). As Plaintiff tells it, Riga knew the BTD application had *zero* prospects of success. *See* ¶ 180. In addition to this "motive's" incoherence, it is also inadequate as a matter of law.[6]

[6] *See, e.g., In re Arrowhead Pharms., Inc. Sec. Litig.*, 782 F. App'x 572, 575 (9th Cir. 2019) (allegations that defendants made false statements in order to secure "a critical, lucrative collaboration deal" and to "raise $43.2 million in a secondary offering" were "allegations of routine corporate objectives" insufficient to support scienter); *Carr v. Zosano Pharma Corp.*, 2021 WL 3913509, at *11 (N.D. Cal. Sept. 1, 2021) (allegations that company "was in desperate need of cash and engaged in regular securities offerings to raise sufficient funds to sustain the Company's operations, including its clinical trials" were "routine corporate objectives" insufficient under Ninth Circuit law); *Twinde v. Threshold Pharms. Inc.*, 2008 WL 2740457, at *15 (N.D. Cal. July 11, 2008) (allegations that defendant pharmaceutical company "was a small company without

Plaintiff has not come forward with the "compelling" and "particularized" facts necessary to plead scienter here. *Prodanova*, 993 F.3d at 1108. Plaintiff's claim that scienter can be inferred because Riga "touched on the specific issue," Opp. at 11, is flawed in multiple respects. In Plaintiff's cases, critical facts establishing the contemporaneous falsity of the defendants' statements existed, and defendants' statements supported their knowledge of those well-pled facts.[7] Here, Plaintiff tries to bootstrap a securities fraud claim by using Riga's broad reference to "statistics" to establish both that the FDA had informed Spectrum of the specific BTD threshold and that Riga knew that information. Riga's vague mention of "statistics" is far afield from the statements at issue in *Reese*. *See* 747 F.3d at 572 (scienter inferred because defendant "ma[de] a *detailed* factual statement"). Finally, Plaintiff misapprehends Defendants' argument regarding their accurate statements about TKIs. Opp. at 11 n.8. Defendants do not contend that scienter requires "patent falsity." Rather, assuming *arguendo* their accurate statements could be deemed misleading, Defendants were at most negligent as to that possibility, and their statements do not reflect the sort of patent falsity that overcomes an inference of mere negligence.

II. *The Opposition Shows Plaintiff's Failure to Plead a ZENITH20 Claim.*

A. The Opposition Confirms Plaintiff's Failure to Plead Falsity.

In dismissing the FAC, the Court recognized the "very stringent pleading standard set forth by Congress," Tr. 97:7-8, and noted Plaintiff's "timeline . . . isn't wholly clear" about "who knew what when." *Id.* 94:12-16; *see also id.* 92:8-14 ("timeline, timeline, timeline"). Plaintiff's SAC does little to correct these deficiencies, merely adding cursory allegations of two uninformed CWs.

i. Plaintiff has not Pleaded that Defendants knew Cohorts 1 and 3 Failed.

For all its sprawling allegations, the SAC's central theory of falsity as to the ZENITH20 statements is simple: at the time of each of their challenged statements, Defendants knew "fully

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any approved products to sell and [drug] was its lead product candidate" insufficient); *Abady v. Lipocine Inc.*, 2023 WL 2938210, at *24 & n.10 (D. Utah Apr. 13, 2023) (need for capital "is a motive that is shared by many small pharmaceutical companies" and is too "generalized" to support scienter).

[7] *See Reese v. Malone*, 747 F.3d 557, 569-70, 572 (9th Cir. 2014); *Washtenaw Cnty. Emps. Ret. Sys. v. Celera Corp.*, 2012 WL 3835078, at *3 (N.D. Cal. Sept. 4, 2012); *Loritz v. Exide Techs.*, 2014 WL 4058752, at *12 (C.D. Cal. Aug. 7, 2014); *Roberti v. OSI Sys., Inc.*, 2015 WL 1985562, at *12 (C.D. Cal. Feb. 27, 2015).

confirmed" "final results" showing that Cohorts 1 and 3 missed their primary endpoints. *See, e.g.*, ¶¶ 111, 195(a), 210. Plaintiff rests that contention on two allegations: (1) Defendants purportedly had final results "within 67 days after final enrollment" (¶¶ 111-112; Opp. at 16); and (2) Defendants' supposedly "admitted" access to the final results (¶¶ 97-99; Opp. at 16-17). The question for the Court is whether those allegations are adequately supported by particularized facts.

First, Plaintiff's 67-day timeline does not come close to passing muster under the PSLRA. Plaintiff concedes its timeline is solely supported by estimates from CW-1, Opp. at 16, who worked as a Research Coordinator in 1 out of the 64 clinical sites, and left that job in March 2018—a full year before even Plaintiff's own timeline alleges Defendants had "access to" the data. ¶¶ 21, 111-112; *see* MTD at 14. Acknowledging the SAC has no further "facts" to offer, Plaintiff responds that "nothing more is required." Opp. at 16. Not so. The Ninth Circuit recently reiterated that securities plaintiffs may not extrapolate from similarly weak factual premises and expect to survive dismissal.[8] *Loc. 282 Pension Tr. Fund & Loc. 282 Annuity Tr. Fund Dist. No. 9 v. Biomarin Pharm., Inc.*, 2024 WL 637491, at *1 (9th Cir. Feb. 15, 2024). There, to substantiate its "crucial" allegation that the study results "predated the challenged statements," the plaintiff relied on the defendants' statements that "[w]e plan to complete preclinical studies in the first half of 2019" and "[drug] has moved beyond the 'Preclinical' stage and has transitioned to human trials." *Id.* The Ninth Circuit held these allegations were insufficient to support "the specific chronology of events" upon which the plaintiff's falsity claims "depend." *Id.* at *2. The plaintiff pled "no facts indicating either that [company] categorically completed all [drug's] preclinical testing by November 2019 or that its transition to human trials ended all such testing." *Id.* at *1. Just as the Ninth Circuit declined to assume that a *defendant's own public estimates* of when preclinical testing would be completed demonstrated when testing was *actually* completed, the Court should not assume that *CW-1's estimates* of the timeline—based on one cohort, at a single clinical site, in ZENITH20's infancy—demonstrates any *actual* timeline of what occurred at least a year later over the expanse of this trial.

[8] The question the Court confronted in *Humphries* was different. *See Sec. & Exch. Comm'n v. Humphries*, 2022 WL 17668022, at *6 (D. Nev. Dec. 13, 2022) (Silva, J.). The defendant argued the SEC's complaint "categorically lumps him in with other defendants" and "fails to allege facts sufficient to place him on notice of the basis for its fraud allegations." *Id.* The Court did not address the issue of whether particularized facts demonstrated that statements were false *when made*.

Plaintiff cannot avoid dismissal by suggesting its timeline could be off only at "the fringes." Opp. at 16. Plaintiff's assumption that the timeline's errors could only be "slight" is emblematic of its impermissibly speculative approach. Plaintiff's fast-and-loose timeline leaves the SAC without particularized facts supporting its allegation that *any* of the challenged ZENITH20 statements were false *when made*. For example, even if Plaintiff's timeline is off by only a few weeks, the April 5, 2019 statements, ¶ 198, are indisputably non-actionable. *See* ¶ 111 (alleging defendants had Cohort 1's final results by March 10, 2019). If the timeline is off by only *three days*, the July 7, 2020 statements, ¶ 209, are indisputably non-actionable. *See* ¶ 112 (alleging defendants had Cohort 3's final results by July 4, 2020). The PSLRA does not permit such imprecision and guesswork.[9]

Second, Plaintiff seeks to rehabilitate its allegations of Defendants' supposed "admissions" that they knew "final" data, *see* MTD at 15-16, by highlighting only a few of Lebel's statements devoid of context. *See* Opp. at 15-16. But those statements are, at most, consistent with the notion—disclosed by Defendants—that Spectrum continually monitored ZENITH20's safety.[10] None establishes the real-time access to complete efficacy data revealing Cohorts 1 and 3 missed the efficacy endpoints that serves as the foundation of Plaintiff's fraud claim.[11]

Under analogous circumstances, courts in this Circuit have not relieved plaintiffs of their heavy PSLRA burden to demonstrate with *particularity* that study data showed falsity. In *Huang*, for example, the plaintiff claimed that the defendants' positive statements about a clinical trial were false because the defendants' interim analysis of safety data allegedly "showed materially negative efficacy." *Huang v. Avalanche Biotechnologies, Inc.*, 2016 WL 6524401, at *6 (N.D. Cal. Nov. 3, 2016). But the court, in dismissing the claim, refused "to speculate about what information besides

[9] The Ninth Circuit in *Biomarin* upheld dismissal of claims through September *2021* because the plaintiff had not adequately supported its falsity theory that study results were known in *2019*. *See Biomarin*, 2024 WL 637491, at *1-2; *see also Arrowhead*, 782 F. App'x at 575 ("Plaintiff has also failed sufficiently to allege falsity with respect to Defendants' failure to disclose, before November 2016, the death of non-human primates in a toxicology study. Plaintiff's factual basis for this claim—that the deaths occurred in 'late 2015 or early 2016'—is not supported by sufficiently specific factual allegations. Thus, Plaintiff's allegations are not sufficient to conclude that Defendants' statements before November 2016 were false.").

[10] *See* Ex. 11 at 16 ("The monitoring of *safety* is on an ongoing basis.").

[11] *See* Ex. 9 at 6 ("[W]e didn't want any *analysis* done on *efficacy* until there's a *full six months follow-up* on the last patient.").

adverse events was contained in the June 2014 interim data analysis, what the results were, and whether *it was analyzed in a way* to predict efficacy in the short or long term." *Id.* at *7.

Similarly, in *CytRx*, the plaintiff claimed that statements that a clinical trial remained "on track" were false because the defendants had data regarding "events" (*i.e.*, death or tumor growth), suggesting they must have known the study's "event rate" was higher than expected, which presented a "highly increased risk of not showing a statistically positive result." *In re CytRx Corp. Sec. Litig.*, 2017 WL 5643161, at *2, *9 (C.D. Cal. Aug. 14, 2017). The court dismissed the claim because, "while this factual allegation demonstrates the Defendants *could* have calculated the event rate and determined . . . the Trial's progress [was] at risk, there is no allegation that Defendants *actually performed these calculations* or had actual knowledge of this risk." *Id.* at *9.

The SAC has no particularized allegation that, prior to Defendants' statements, the data collected from hundreds of patients at 64 medical centers on three continents had been aggregated and statistically analyzed to confirm the composite ORR, let alone that any Individual Defendants knew it. *See Dresner v. Silverback Therapeutics, Inc.*, 2023 WL 2913755, at *10 (W.D. Wash. Apr. 12, 2023) (refusing to infer "clinical sites located in three countries were continuously cleaning and aggregating data, reviewing it, and summarizing it"). Plaintiff has no answer to this authority other than *Puma*, Opp. at 18, which only solidifies that Plaintiff's allegations are not enough.[12]

Third, the weak CW allegations are more notable for what they do not say than what they do. CW-1's carefully worded allegations (¶¶ 21-35) state only that at one clinical site prior to March 2018, individual patient data was uploaded to the EDC system, that some subset of Spectrum personnel "inquired" about and reviewed it, and that CW-1 was not aware of restrictions on who could see it. CW-1 never alleges that those "inquiries" related to efficacy or ORRs—as opposed to ensuring data integrity, as indicated by CW-1's allegations that Spectrum personnel compared patient charts to data entered into the EDC "to make sure the two data sets were consistent." And CW-1's account of discussions involving "the results of other clinical sites" were about "side effects" and "AEs"—allegations consistent with Spectrum's monitoring of safety. CW-1 also

[12] In *Puma*, the defendant admitted to seeing the *exact* data demonstrating falsity, and did not deny it; the issue was instead whether the statements were literally false. *See Hsu v. Puma Biotechnology, Inc.*, 213 F. Supp. 3d 1275, 1287 (C.D. Cal. 2016).

recalls an unspecified newsletter containing information about "AEs and efficacy," but does not suggest it conveyed that Cohorts 1 and 3 had or were poised to miss their endpoints (nor could it do so, as CW-1's knowledge ends in March 2018, so this newsletter must predate that time). Finally, CW-1 claims to have discussed "the results of each scan" for individual patients at weekly meetings, but does not claim anyone at Spectrum discussed or analyzed any aggregated or final data.

CW-2 likewise carefully alleges (¶¶ 36-47) that "open" trials have less "restrictions" on "*who at the Company* had access to data"—consistent with the notion that only a subset of personnel had data access. CW-2 also alleges the EDC contained "efficacy graphs and safety printouts," but does not explain what those are or what they showed. CW-2 alleges Lebel "knew that the Pozi dose was too high," even claiming that Lebel "described his concern" in "several meetings," but offers no description whatsoever as to the alleged reasons for Lebel's comments. Indeed, CW-2 does not claim that Lebel discussed ORRs, efficacy, or any trial results at all. CW-2 also never claims to have communicated anything of the sort to Lebel.

These factual gaps preclude a determination that they support a claim of falsity.[13]

ii. Plaintiff Pleads No Actionable Omission as to Adverse Events.

Plaintiff's effort to buttress insufficient allegations of "dramatic" AEs fails. Opp. at 19. Numerous cases hold that interim FDA feedback or criticism does not render positive statements about a clinical trial misleading.[14] And *Christiansen* does not hold differently; there, the court *dismissed* the plaintiff's claims implicating Spectrum statements about "tolerability" and "adverse events." *See Christiansen v. Spectrum Pharms., Inc.*, 2024 WL 246020, at *11-12 (S.D.N.Y. Jan. 23, 2024) (citing *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016)). More to the point, Plaintiff pleads no

[13] *See In re Arrowhead Pharms., Inc. Sec. Litig.*, 2017 WL 8791111, at *5 (C.D. Cal. Dec. 21, 2017), *aff'd*, 782 F. App'x 572 (9th Cir. 2019) ("The Court agrees with Defendant that 'if Plaintiffs actually had a basis to claim this employee was supervising the pre-clinical and clinical studies they would say so.' Even if he did supervise the trials, Plaintiffs have still not provided specifics about what caused the deaths and a more specific window for when they occurred."); *Brodsky v. Yahoo! Inc.*, 630 F. Supp. 2d 1104, 1116 (N.D. Cal. 2009) ("CW 16 was in a position to provide a personal account of how Defendants falsified $680 million in revenue; however, she/he does not provide any particular facts to support revenue fraud allegations.").

[14] *See In re Arrowhead Pharms., Inc. Sec. Litig.*, 2017 WL 5635422, at *5 (C.D. Cal. Sept. 20, 2017) ("Plaintiffs allege that Defendant omitted that the FDA had placed the hold due to 'concerns over toxicity,'" but "courts have held that such details need not be disclosed."); *Pardi v. Tricida, Inc.*, 2024 WL 1056013, at *7 (N.D. Cal. Mar. 11, 2024) (similar); *Strezsak v. Ardelyx Inc.*, 2024 WL 1160900, at *6 (N.D. Cal. Mar. 18, 2024) (similar).

facts showing the FDA had expressed concerns about Cohorts 1 or 3, and no facts showing that any Defendant knew AEs had or would cause Cohorts 1 and 3 to miss the efficacy endpoints—or even any facts showing that AEs *did* cause Cohorts 1 and 3 to miss the efficacy endpoints.[15]

iii. Plaintiff Pleads No Actionable Omission about the MD Anderson Study.

Plaintiff barely responds on this theory, and cites no authorities. There is no duty to disclose that "multi-centered trials perform worse," *Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996), and especially not here, where all relevant information was known to investors. MTD at 19-20. Lebel's *disclosure* that single-center trial data is "often a little better" cannot prop up Plaintiff's illogical leap to the conclusion that ZENITH20 was doomed from the start. ¶ 185.

B. Defendants' Puffery Statements are Non-Actionable.

Plaintiff maintains that Defendants' generalized optimistic statements were not puffery, Opp. at 20, but fails to identify any "integral" "representation" that approaches anywhere near the level of specificity of the contextual statements in *Casella*. *See Casella v. Webb*, 883 F.2d 805, 806-08 (9th Cir. 1989) (description of investment as "sure thing" not puffery where used to emphasize specific representations that the investment was an IRS-approved tax shelter and that $41,000 investment over three years would result in a tax credit making investment profitable). And *Quality Systems* involved far more specific statements about "the number and type of prospective sales" in a pipeline that the defendants "knew"—based on detailed factual allegations absent here—"to be performing poorly." *See* 865 F.3d at 1143-44.

C. Defendants' Forward-Looking Statements are Protected by the Safe Harbor.

Plaintiff argues that the supposed "present-tense" portions of forward-looking statements are not eligible for safe harbor protection. Opp. at 20. But under the Ninth Circuit's holistic approach, the statements are still forward-looking "because, *examined as a whole*, the challenged

[15] The problems with Plaintiff's CWs go well beyond hearsay. Opp. at 19. CW-1's "understanding" that Pozi failed because of "toxicity and the AEs," ¶ 31, is unmoored in time and does not connect that "understanding," *ad hoc* or not, to any Individual Defendant. CW-2's similar "understanding," ¶ 47, is also untethered to any Individual Defendant, but merely purports to establish a general "awareness" within Spectrum. *See Ezzes v. Vintage Wine Ests., Inc.*, 2024 WL 895018, at *8 (D. Nev. Mar. 1, 2024) (discrediting CW allegations of "general consensus" and noting "even if the statements were credited as reliable," individual defendants were "not alleged to have been informed"); *Veal v. LendingClub Corp.*, 423 F. Supp. 3d 785, 800, 814 (N.D. Cal. 2019) (similar).

statements related to future expectations and performance." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1059 (9th Cir. 2014).[16] To the extent Plaintiff argues Defendants' statements also were "reciting current and past facts [that] are not protected by the safe harbor," *Quality Sys.*, 865 F.3d at 1141-42, Plaintiff does not plead those current and past facts were false.[17]

Moreover, Plaintiff's labeling of Defendants' cautionary language as "boilerplate," Opp. at 21, ignores that courts both inside and outside this Circuit have held that near identical language sufficed to invoke the safe harbor. *See* MTD at 21; *In re Nuvelo, Inc., Sec. Litig.*, 2008 WL 5114325, at *16 (N.D. Cal. Dec. 4, 2008) (holding caution that "[r]esults attained in pre-clinical testing and early clinical studies, or trials, may not be predictive of results that are obtained in later studies" was meaningful); *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 404-05 (S.D.N.Y. 2018), *aff'd*, 757 F. App'x 35 (2d Cir. 2018) (similar).

Finally, Plaintiff does not adequately allege Defendants had the requisite actual knowledge or knew the warned of risks had "already materialized," Opp. at 21, for the reasons explained above.

D. Defendants' Opinion Statements are Non-Actionable.

Because Plaintiff's only grounds to challenge Defendants' opinion statements is their supposed knowledge that ZENITH20 "failed," Opp. at 22, Plaintiff has failed to state a claim. *See In re Regulus Therapeutics Inc. Sec. Litig.*, 406 F. Supp. 3d 845, 857 (S.D. Cal. 2019) (opinions non-actionable where plaintiff "failed to provide specifics" or a "particularized description of the relevant analysis and findings" of studies that purportedly contradicted defendants' statements).

E. The Opposition Confirms Plaintiff's Failure to Plead Scienter.

Held to the PSLRA's exacting requirements, Plaintiff does not plead scienter.

CWs. Plaintiff makes three ineffective excuses for its inadequate CW allegations. First it suggests it need not establish that the Defendants "actually received or reviewed" information contradicting their statements. Opp. at 17 n.12. But courts routinely require just that.[18] Plaintiff also

[16] *See also Wochos*, 985 F.3d at 1196 ("Tesla's unadorned comment . . . that its 'preparedness at this time' would allow it to achieve its year-end goal does not go beyond what is inherent in declaring any forward-looking objective.").

[17] For example, Plaintiff does not plead that Defendants did not in fact "monitor safety on all [their] studies," or that Defendants did not "prophylax every patient." Opp. at 20 (citing ¶¶ 201, 217).

[18] *See, e.g., Zaidi v. Adamas Pharms., Inc.*, 650 F. Supp. 3d 848, 862 (N.D. Cal. 2023) ("[Plaintiff] does not allege [defendant] actually received that information; he merely states [CW] would have

claims it is immaterial that the CWs did not "interact" with Individual Defendants "directly." Opp. at 18 n.13. But Plaintiff's authorities still contained allegations that *directly* tied the relevant information to the individuals.[19] Plaintiff lastly insists the SAC "describes the data in detail." Opp. at 18 n.14. That is simply not the case. CW-1's general description, by category, of certain data on individual patients does not address the critical inquiry: whether either cohort's data was aggregated and statistically analyzed to confirm composite ORRs at any point before Defendants' statements.[20]

***Core Operations*.** Plaintiff's core operations theory fails on this basis too. "[T]o demonstrate scienter under the core operations doctrine," Plaintiff "must assert particularized allegations about the who, what, where, when, and how regarding each Defendant's access to the relevant information." *Lopes v. Fitbit, Inc.*, 2020 WL 1465932, at *11 (N.D. Cal. Mar. 23, 2020); *accord In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1063-64 (9th Cir. 2014); *Ezzes v. Vintage Wine Ests., Inc.*, 2024 WL 895018, at *12 (D. Nev. Mar. 1, 2024). Plaintiff pleads no such facts. *See* ¶¶ 266-274. Nor is it "absurd" that Defendants would not personally review granular patient data, but would instead await the reports of a central imaging lab and data review committee. Opp. at 23.

***Individual Stock Sales*.** Plaintiff claims the Individual Defendants made "unusual" or "suspicious" stock sales without setting forth sufficient facts to support those claims. *First*, "[t]he weight of authority in the Ninth Circuit holds that courts can consider 10b5-1 trading plans when evaluating allegations concerning scienter." *Pardi v. Tricida, Inc.*, 2022 WL 3018144, at *15 (N.D. Cal. July 29, 2022); *see Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1067 n.11 (9th Cir. 2008); *Curry v. Yelp Inc.*, 875 F.3d 1219, 1226 n.2 (9th Cir. 2017). That Defendants' plans may have gone "into effect during the Class Period," Opp. at 25, is immaterial here, where the

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been 'surprised' if [defendant] did not have it"); *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, 2019 WL 6877195, at *19 (N.D. Cal. Dec. 17, 2019) ("The CWs lack personal knowledge as to whether [defendants] read or heard of the internal information and presentations—and therefore cannot be relied upon to establish scienter").

[19] *See Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 772 (9th Cir. 2023) (CW alleged "the pressure campaign came directly from [individual defendant]"); *Quality Sys.*, 865 F.3d at 1145 (CW personally "arranged for sales reports to be automatically delivered to the CFO").

[20] *See Wozniak v. Align Tech., Inc.*, 850 F. Supp. 2d 1029, 1042 (N.D. Cal. 2012) ("[A]lthough plaintiff referred to the existence of sales and shipment data and made a general assertion about what the data showed, plaintiff alleged no hard numbers or other specific information."); *Intuitive Surgical*, 759 F.3d at 1063 (rejecting CW allegations that "provide only snippets of information").

10b5-1 sales were still made automatically for tax withholding purposes.[21] *See* MTD at 34.

Second, Plaintiff's own allegations in fact show the "suspicious" sales to be consistent with the Individual Defendant's other sales during the Class Period (and consistent with tax withholding sales made on an executive incentive plan that vests periodically and often at regular intervals). For example, 13 of the 19 "suspicious" sales occurred in late March or early April in 2019 and 2021. ¶¶ 259, 263. Plaintiff's Appendix E shows those same Defendants made 17 sales in that same late-March/early-April timeframe of 2018 and 2020. The latter, according to Plaintiff, are not suspicious. Opp. at 24 n.18. Similarly, Plaintiff alleges it was "suspicious" that Lebel sold 6,963 shares on November 6, 2019, but *not* suspicious that he sold 7,025 shares on November 6, 2020. Other "suspicious" sales consist of: Gustafson's sale of 25,696 shares on December 14, 2020 (but *not* his sale of 33,692 shares on January 11, 2019); Turgeon's sales in May and June 2019 totaling 40,942 shares (but *not* his sales in January 2019 totaling 41,402 shares); and Turgeon's November and December 2020 sales (but *not* his large April 2018 or January 2019 sales).

***Spectrum's Stock Sales*.** Plaintiff's portrayal of Spectrum stock sales as "suspiciously launched," Opp. at 26, is unsupported by the requisite factual allegations. *See Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1006 (9th Cir. 2009) (to create strong scienter inference, corporate stock sales must be "uncharacteristic" or "inconsistent with the corporation's traditional business practices"). Here, Plaintiff pled no facts to meet its burden, because it could not. The alleged ATM financings were "business as usual" for Spectrum. *See* Ex. 26 at 4, 6, 8-9. And Spectrum's so-called "existential need for cash," Opp. at 26 n.20, makes no difference. *Supra* p. 5 n.6 (collecting cases).

***Executive Departures*.** Plaintiff's one-sentence assertion that two executive departures were "suspicious" also lacks support. Opp. at 27. Turgeon retired a full year after Spectrum announced Cohort 3's results, and Gustafson resigned another year after that. ¶¶ 14-15.

[21] Plaintiff also claims the Form 4s "contradict the footnote" regarding the trading plans. Opp. at 25. But as the SEC instructions plainly state, an "F" designation is only to be used when "withholding securities" for tax purposes. Stein Decl. Ex. B at 7. An "S" is used for any sale of the security, regardless of the purpose of that sale. In other words, "F" denotes that the shares themselves were withheld, while "S" means a sale occurred, even if the sale was to generate proceeds to be withheld. *Compare, e.g.*, Ex. 33 at 3, *with* Ex. 33 at 4.

Holistic Review. Even added up, Plaintiff's allegations of routine stock sales, corporate financings, and executive departures cannot resuscitate the SAC's speculative fraud claims.

III. *The Opposition Shows Plaintiff's Failure to Plead a Rolontis Claim.*

A. The Opposition Confirms the BLA Withdrawal Claim Should Be Dismissed.

Unable to deny that all material information was disclosed, Plaintiff instead chides Defendants for not using descriptors like "ultimatum" or "forced." *See* Opp. at 28. But statements are not false or misleading "simply because [they] do not use the eye-catching or negative phrasing that plaintiffs would have wished." *Singh v. Schikan*, 106 F. Supp. 3d 439, 448 (S.D.N.Y. 2015). Defendants expressly told investors the BLA application was withdrawn due to the *FDA's* "request for additional" "*required*" information that Spectrum *could not provide* by the *FDA's* deadline. ¶ 229; *see also* Opp. at 28 (ignoring this language). "And even accepting the Plaintiff's position that there was a material difference nonetheless, it was not such that one might reasonably infer scienter from [Defendants'] failure to elaborate more fully." *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 59 (1st Cir. 2018). Tacking on dubious "motive" allegations does not make Plaintiff's weak scienter inference any more compelling. *Id.*; *see* Opp. at 29.

B. The Opposition Confirms the Hanmi Inspection Claim Should Be Dismissed.

i. The SAC Does Not Plead Falsity with Particularity.

Plaintiff allots just one paragraph to supporting its conclusory claim that Defendants' pre-Hanmi inspection statements were false when they were made. *See* ¶ 44. Specifically, the only supposed "facts" Plaintiff pleads are (1) Spectrum supposedly failed two mock inspections—out of how many, Plaintiff does not say—at least 8 to 11 months before the FDA's inspection, and (2) CW-2's unadorned comments about Hanmi and Spectrum's lack of "control" over Hanmi's facility. *See id.*; MTD at 29-30. This does not even begin to approach meeting the PSLRA's exacting pleading burden. *See Espy v. J2 Glob., Inc.*, 99 F.4th 527, 537 (9th Cir. 2024) (rejecting CW allegations that amounted to mere "criticisms" and "negative opinions").[22]

[22] *In re Am. Apparel, Inc. S'holder Litig.* is a much different case. *See* 2013 WL 10914316, at *4-5, *14-15 (C.D. Cal. Aug. 8, 2013) ("sheer magnitude" of immigration violations—84.5% of American Apparel employees with alien numbers were undocumented and company lost 2,500 out of 3,500 manufacturing employees—corroborated CW allegations).

Rather than lend credence to Plaintiff's claims, Plaintiff's marquee case gives a roadmap of the SAC's deficiencies. Opp. at 30 (discussing *Salzman v. ImmunityBio, Inc.*, 2024 WL 3100274 (S.D. Cal. June 20, 2024)). That plaintiff adequately alleged statements that "[w]e have established Good Manufacturing Practice (GMP) manufacturing capacity at scale" were false when made in light of extensive detailed allegations that, *inter alia*: the company received "three separate Forms 483" from the FDA identifying numerous deficiencies; the FDA notified the company it would conduct a lengthier inspection than typical; the company entered a stringent Quality Agreement with the manufacturer with onerous reporting obligations through which it learned of continuous problems; the CEO held monthly meetings with the manufacturer to discuss ongoing, pervasive issues; and nonetheless, the issues did not stop, but resulted in "frequent supply delays for the company's flagship product that lasted for months." *Salzman*, 2024 WL 3100274, at *2-4, *8-9.

ii. The Forward-Looking Statements are Non-Actionable.

Plaintiff's arguments to the contrary are unavailing for several reasons. *First*, Plaintiff's claim that Defendants' statements were not forward-looking because they "expressed current or past facts" regarding readiness, Opp. at 32, is foreclosed by Ninth Circuit precedent. *See Wochos*, 985 F.3d at 1192, 1196. *Second*, courts in this Circuit are split over whether omissions fall outside of the safe harbor, but the Court need not reach that issue because Plaintiff fails to plead with particularity any actionable omission.[23] *Third*, Defendants' cautionary language meets the level of specificity required by the Ninth Circuit. *See* MTD at 31.[24] *Fourth*, that Defendants referenced "mock inspections" cannot plead falsity, let alone "actual knowledge," where the SAC has no particularized facts supporting that Spectrum failed any such inspections, let alone when or why. *See* Opp. at 32-33.

[23] *See In re Intel Corp. Sec. Litig.*, 2023 WL 2767779, at *18 (N.D. Cal. Mar. 31, 2023); *supra* § III.B.i. If the Court reaches the issue, the Court should not adopt the reasoning in *STAAR*, as it is contrary to the PSLRA's plain language. *See Melot v. JAKKS Pac., Inc.*, 2016 WL 6902093, at *24 (C.D. Cal. Nov. 18, 2016) ("[Safe harbor statute] specifically provides that, as to forward-looking statements, both an 'untrue statement of material fact' and an '*omission* of a material fact . . .' are subject to immunity under the PSLRA if accompanied by meaningful cautionary language.").

[24] *See In re Cutera Sec. Litig.*, 610 F.3d 1103, 1112 (9th Cir. 2010) ("ability to continue increasing sales performance worldwide" "spoke directly to" misstatements about "significant shortcomings of the junior sales program"); *Intuitive Surgical*, 759 F.3d at 1059 (similar); *see also* Exs. 30-31.

iii. The Opinion Statements are Non-Actionable.

Plaintiff's conclusory allegations also doom its effort to plead any actionable opinion. Opp. at 32-33. Even crediting CW-2's unsubstantiated claims of two failed mock inspections, "[t]he SCAC does not contain sufficient factual allegations demonstrating that Defendants knew the extent of [manufacturing issues] or whether this [issue] was actually pervasive enough" to render Defendants' statements misleading. *See Bien v. LifeLock Inc.*, 2015 WL 12819154, at *4 (D. Ariz. July 21, 2015), *aff'd*, 690 F. App'x 947 (9th Cir. 2017).

iv. The Opposition Confirms Plaintiff's Failure to Plead Scienter.

Plaintiff fails to plead scienter for much the same reasons. The SAC does not "allege any specific facts that give rise to a strong inference that the defendants . . . knew there were problems of such magnitude that it would make their positive statements false." *See In re Siebel Sys., Inc. Sec. Litig.*, 2005 WL 3555718, at *4 (N.D. Cal. Dec. 28, 2005).

Plaintiff's resort to "temporal proximity" is irrelevant. *See Yourish v. California Amplifier*, 191 F.3d 983, 997 (9th Cir. 1999) (holding temporal proximity can "bolster" well-pled claims but affirming dismissal where "there are no other adequately pleaded allegations for the temporal proximity to bolster"). Plaintiff also again clings to core operations, but does not plead the necessary predicates. *See Aramic LLC v. Revance Therapeutics*, 2024 WL 1354503, at *15 (N.D. Cal. Apr. 2, 2024) (doctrine requires "allegation[s] of specific information conveyed to management," and holding it was not "absurd to suggest" defendants were unaware of deficiencies "while making positive statements about the BLA and FDA inspection"); *NVIDIA*, 768 F.3d at 1064 (doctrine inapplicable even where "the problem concerned [company's] flagship product").[25] The individual and corporate stock sale theories also fail as discussed above, leaving only CW-2's bare claim that Hanmi "failed the mock inspections a couple of times," Opp. at 34-35; ¶ 44.

CONCLUSION

For the foregoing reasons, the SAC should be dismissed with prejudice.

[25] Plaintiff's authorities, Opp. at 34, reflect its pattern of citing cases with detailed and specific factual allegations, which merely expose just how far Plaintiff leaps to try to reach its conclusions here. *See, e.g.*, *Mulligan v. Impax Lab'ys, Inc.*, 36 F. Supp. 3d 942, 955, 970 (N.D. Cal. 2014) (management received "repeated Form 483s" from the FDA and CW "regularly met in person on a weekly basis" with individual defendant).

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of Pisanelli Bice PLLC, and that on this 22nd day of July, 2024, I caused to be e-filed/e-served with the Court's CM/ECF system true and correct copies of the above and foregoing **DEFENDANTS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT** to all parties registered for service.

/s/ Kimberly Peets
An employee of Pisanelli Bice PLLC